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10/675,927	09/29/2003	Payman Amiri	18773.004	2378

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,927	AMIRI ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *74-84 and 87-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *74-84, 107* is/are rejected.

7)☒ Claim(s) *87-106* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 05/15/2006, wherein claims 74-75, 78, 82 have been amended, claim 86 has been canceled. Amendment also added new claims 87-107.

Applicant's cancellation of Claim 86 is sufficient to overcome the rejection of claim 86 under 35 U.S.C. 112, and 35 U.S.C 101.

The rejection of claims 76, 80, 83 under 35 U.S.C. 112, first paragraph, because the specification while being enabling for specific agent selected from irinotecan, topotecan, gemcitabine, 5-fluorouracil, leucovorin, carboplatin, cisplatin, taxanes, tezacitabine, cyclophosphamide, imatinib, specific anthracyclines, rituximab, trastuzumab for the treatment of specific cancer disorder mediated by Ras mitogen activated protein kinase pathway, **does not reasonably provide enablement for the method of treating cancer in a human or animal subject** comprising administering a compound represented by formula (I), and agents in general is MAINTAINED. Note applicant did not comment on this rejection.

Claims 74-84, and 87-107 are pending, and examined herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Objections

Claims 87-106 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the

alternative only. See MPEP § 608.01(n). Accordingly, the claims 87-106 are not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 75-84, and 107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating some particular/specific cancer disorders in a human or animal comprising administering a composition comprising instant compounds represented by formula (I), **does not reasonably provide enablement for treating any cancer disorder in general** mediated by Ras mitogen activated protein kinase pathway. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating a cancer disorder in a human or animal subject, comprising administering a composition comprising a compound represented by formula (I). The nature of the invention is complex in that it encompasses the treatment of **any type of cancers in general** mediated by Ras mitogen activated protein kinase pathway.

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass treatment of **any number of cancers** mediated by Ras mitogen activated protein kinase pathway, comprising administering a composition comprising a compound represented by formula (I). What's more, the scope of the compounds claimed to be useful for the treatment of cancer is extremely broad. The instant claims are deemed very broad since these claims read on a method of treatment of any cancer by inhibiting Raf kinase activity.

(3). Guidance of the Specification / (4). Working Examples::

The specification does not provide any guidance as to how one would administer the claimed compositions comprising instant compounds to a subject and treat **any** type of cancer cell.

All of the guidance provided by the specification is directed towards the synthesis of the compounds represented by formula (I). Applicant provides in the specification on pages 307-309 *in vitro* assay protocol, Raf Screening in general. The specification discloses on page 309 "Using the procedures of Examples 1401 or 1402, the compounds of Examples 1-1094 were shown to have a raf kinase inhibitory activity at an IC_{50} of less than 50 μM."

(5). State of the Art:

While the state of the art is relatively high with regard to treating specific cancers mediated by Ras mitogen-activated protein kinase signal pathway, the state of the art with regard to treating **any cancer disorder** generally is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers. Carter, et al. (Chemotherapy of Cancer, 2nd ed., 1981) clearly teaches that for the forty known anticancer agents, none are effective against all cancers (pages 362-365). There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-I), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide

variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Even those that affect a single organ are often not generally treatable. For example, the main types of lung cancer are small cell (oat cell), giant cell, clear cell, adenocarcinoma of the lung, squamous cell cancer of the lung, and mesothelioma. There is no such thing as a treatment of these generally because of their diversity. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

(6). Predictability of the Art:

The invention is directed to treatment of cancer in general mediated by Ras mitogen-actived protein kinase signal pathway by administering a composition comprising a compound of formula (I).

It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970). Cancers are especially unpredictable due to their complex nature. Please refer to the discussion of Carter, et al. and the state of the art in (5) that shows the different treatments of cancers. The treatment of one type of cancer could not be necessarily the same for the other type. Thus, the instant claimed invention is **highly unpredictable**.

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a compound, a dosage for each compound, an appropriate pharmaceutical carrier, the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the compound in the model system to determine whether or not the compound is effective for inhibiting cancer cells. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding treatment of cancer with any compound, one of skill in the art would have to then either envision a modification of the first pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, and test the system again. In order to practice Applicant's invention, it would be necessary for one to conduct the preceding experimentation for each type of cancer because, as described by Carter, et al., there is no known drug effective for treating all types of cancer. Therefore, it would require **undue, unpredictable experimentation** to practice the claimed invention to treat **any** cancer disorder mediated by Ras/mitogen-activated protein kinase signal pathway in a human or animal subject by administration a composition comprising one of the compounds represented by formulas (I).

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, a method for treating a **cancer in general** mediated by Ras mitogen activated protein kinase pathway by administering the various compounds represented by formula (I) is not considered to be enabled by the instant specification.

Response to Applicant's arguments:

Applicant remarks that "at the time of filing of the present application, the role of Ras, and the utility of inhibitors of Raf kinase in the treatment Ras/mitogen-activated protein kinase (MAPK) signaling pathway-mediated cancers, such as melanoma, lung cancer pancreatic cancer, thyroid cancer, bladder cancer, colon cancer, liver cancer, myeloid leukemia and villous colon adenoma, was established in the art. As stated in de Bono et al. (see footnote 2) was published in the art." These remarks have been considered, and acknowledged herein. It is respectfully pointed out that the claims are directed to any cancer mediated by Ras mitogen-activated protein kinase signal pathyway, and not to those that are disclosed in Bono et al. Further, it is respectfully pointed out that applicant's specification merely recites that the compounds of Examples 1-1094 were shown to have a raf kinase inhibitory activity at an IC_{50} of less than 50 μM. The applicant has not provided any competent evidence that the instantly disclosed tests are highly predictive for all types of cancers disclosed and embraced by the claim language for the intended host. Further, there is no known anticancer agent which is effective against all cancers by inhibing Raf kinase activity. Carter, et al. (Chemotherapy of Cancer, 2nd ed., 1981) clearly teaches that for the forty known anticancer agents, none are effective against all

cancers (pages 362-365). There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76, 80, 83 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for specific agent selected from irinotecan, topotecan, gemcitabine, 5-fluorouracil, leucovorin, carboplatin, cisplatin, taxanes, tezacitabine, cyclophosphamide, imatinib, specific anthracyclines, rituximab, trastuzumab for the treatment of specific cancer disorder mediated by Ras mitogen activated protein kinase pathway, **does not reasonably provide enablement for the method of treating cancer in a human or animal subject** comprising administering a compound represented by formula (I), and **agents in general**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope** with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treating a cancer disorder in a human or animal comprising administering a composition comprising a compound represented by formula (I), and **any agent** for treating cancer. The nature of the invention is complex in that it encompasses the treatment of cancer comprising administering a compound represented by formulas (I) with a wide array of **various agents.**

(2). Breadth of the Claims:

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass treatment of any cancer mediated by Ras mitogen activated protein kinase pathway, by

administering a composition comprising a compound of formula (I) with **any** agent for treatment of cancer.

(3). Guidance of the Specification / (4) Working Examples:

There is no guidance given by the specification as to what type of formulations comprising a compound of formula (I) and an agent would be effective for the treatment of cancer. Pages 8-9 of the specification describes **agents** that can be used in combination with a composition comprising a compound represented by formulas (I) to (V) broadly as any suitable anticancer agents such as agents that induce apoptosis; polynucleotides; alkylating agents etc.

(5). State of the Art:

While the state of the art is relatively high with regard to specific anti-cancer agent, the state of the art with regard to anti-cancer agents in **general** is underdeveloped. Different agents have different chemical structures and are expected to behave in different manners. The level of skill in this art is low relative to the difficulty of the task of determining a composition comprising instant compound in combination with a suitable anti-cancer agent for the treatment of cancer.

(6). Predictability of the Art:

The invention is directed to **agents in general**. It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

Chemotherapeutic agents are especially unpredictable due to their complex nature.

It is further noted that the pharmaceutical art is **unpredictable**, requiring each embodiment to be individually assessed for physiological activity. In the instant case, the claimed invention is highly **unpredictable**. For example anti-cancer agents such as 5-Fluorouracil, Gemcitabine, etoposide, doxorubicin, Cisplatin etc. have very different structures and thus will possess different properties such as binding affinities, solubilities etc. Thus one skilled in the art would recognize that the combination of these anti-cancer agents with instant compound represented by formulas (I) to (V) is highly unpredictable with regards to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions. One of skill in the art would not be able to fully predict the possible treatments herein and possible adverse effects occurring with many agents having the claimed functional properties and their combinations to be administered to a host in the claimed method herein. Thus, the instant claimed invention is **highly unpredictable**.

(7). The Quantity of Experimentation Necessary:

In order to practice the claimed invention, one of skill in the art would have to first envision a combination of specific agent with a compound of instant formula (I), pharmaceutical carrier, a dosage for each chemotherapeutic agent, the duration of treatment, route of treatment, etc. One would then need to test the combination in the model system to determine whether or not the combination is effective for inhibiting cancer cells and one would need to test for side effects and

toxicity. If the treatment is unsuccessful, one of skill in the art would have to modify the first combination with another chemotherapeutic agent, dosage, duration of treatment, route of administration, and sequence of administration etc. Even if successful, however, one of skill in the art would then need to determine the magnitude of the side effects and toxicity of utilizing a compound of formula (I) in combination with the agent. One would then need to determine whether or not the magnitude of the side effects could be reduced by increasing or decreasing the dosage of one or both of the agents while retaining the functional aspect of the combination. Once the functionality to toxicity ratio was maximized, one would need to determine whether or not the combination which had been used was of sufficient benefit that it would serve as a useful conditioning combination. If not, one would need to select another agent and repeat the process until a sufficient benefit to detriment ratio had been achieved.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 74 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of treating a specific disease mediated by Raf kinase activity, does not reasonably provide enablement for treating **any** disease in general mediated by Raf kinase activity by administering a composition comprising a compound of Formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention **commensurate in scope with these claims**.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification does not provide sufficient information that all diseases are treatable with pharmaceutical composition comprising compound of Formula I, described in the method claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the

presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). The Nature of the Invention:

All of the rejected claims are drawn to an invention which pertains to a method of treatment of a disease by administering a composition comprising compound of formula (I). The nature of the invention is complex in that it encompasses the treatment of **all diseases** mediated by Raf kinase activity comprising administering a composition comprising a compound of formula (I).

(2). Breadth of the Claims:

The claims are very broad. The claims would reasonably encompass any disease mediated by Raf kinase which could be the **treatment of unknown diseases** in a mammal by administering a pharmaceutical composition comprising compound of formula (I). The coverage of diseases in the claim is immense. The breadth of the claims includes hundreds of diseases mediated by Raf kinase activity.

(3). Guidance of the Specification /(4). Working Examples::

The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treat any disease is limited. All of the guidance given in the specification on pages 307-309 is *in vitro* assay protocol, Raf Screening in general.

There are no working examples for the treatment of a disease using compositions comprising compounds of formula (I).

(5). State of the Art:

While the state of the art is relatively high with regard to treating specific disease, the state of the art with regard to treating **any disease** mediated by Raf kinase activity generally is underdeveloped. In particular, there is no known compound which is effective against all diseases. For example, there are compounds that treat a range of diseases, but no one has ever been able to figure out how to get a compound to be effective against any disease generally. Thus, the existence of such a "silver bullet" is contrary to our present understanding in pharmaceutical art. See Carter et al. discussed above for the treatment of cancer.

(6) The predictability or unpredictability of the art:

The invention is directed to treatment of any disease in general. It is well established that "the scope of enablement various inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839 (1970).

In the instant case the unpredictability of the art is very high because there are thousands of diseases which have fundamentally different mechanism and different causes. The method of diagnosing or treating one disease or condition does not necessitate the treatment or diagnosis of another disease or condition since diseases and conditions have unique chemical pathways by which they are expressed. Additionally, a single disease or condition can be diagnosed via multiple biochemical pathways and treated via multiple biochemical pathways. Thus, the treatment and diagnosis of diseases and conditions is highly

unpredictable. Further as discussed above, for example a method of treating a disease such as cancer is unpredictable due to their complex nature. Please refer to the discussion of Carter, et al. and the state of the art in (5) that shows the different treatments of cancers. The treatment of one type of cancer could not be necessarily the same for the other type. Thus the treatment of **any disease** by inhibiting Raf kinase activity in a human or animal subject by administering compounds represented by formula (I) is highly unpredictable with regard to therapeutic effects.

(7). The Quantity of Experimentation Necessary:

Since every disease and disorder has its unique chemical pathway of expression, diagnosis and treatment of individual diseases and condition cannot be predicted a priori but must be determined from case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine which compounds of formula (I) treats which diseases/conditions. For example, chemical modification of biomolecules may alter the biological property that is important in the use of that particular, and also other properties such as solubilities in aqueous media, binding affinities etc. Thus variety of compounds encompassed by structure (I) will have different biological properties. Considering variety of compounds covered by formula (I) and the multitude of different diseases to be treated, this is a very large degree of experimentation.

In order to practice the claimed invention, one of skill in the art would have to first envision a compound of Formula I, a dosage for each, the duration of treatment, route of treatment, etc. and, in the case of human treatment, an appropriate animal model system for one of the claimed compounds. One would then need to test the compound in the model system to determine whether or not the compound is effective for inhibiting Raf kinase activity. If unsuccessful, one of skill in the art would have to then need to envision a modification of the compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, and test the system again. In order to practice Applicant's invention, it would be necessary for one to conduct the preceding experimentation for each type of disease because there is no known drug effective for treating all types of diseases. Therefore, it would require **undue, unpredictable experimentation** to practice the claimed invention to treat **any** disease in a mammal by administration of a pharmaceutical composition of Formula I.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, a method for treating **any disease in general** mediated by Raf kinase activity by administering a composition of formula (I) of the claims is not considered to be enabled by the instant specification.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni
Patent Examiner
Art Unit 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER